

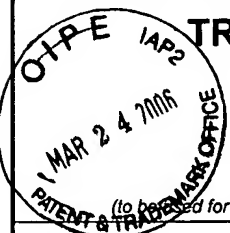
03-27-06

PTO/SB/21 (09-04)

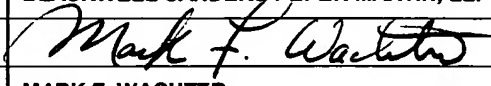
Approved for use through 07/31/2006. OMB 0651-0031

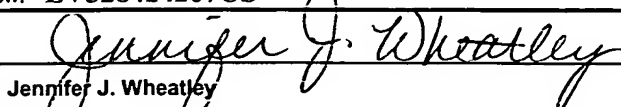
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

 <b>TRANSMITTAL FORM</b>	Application Number	10/709,870	
	Filing Date	June 2, 2004	
	First Named Inventor	Mitchell I. Kirschner	
	Art Unit	1616	
	Examiner Name	Frank I. Choi	
Total Number of Pages in This Submission	175	Attorney Docket Number	718689.78

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Documents <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Receipt Postcard References Cited (170 pgs.)
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	BLACKWELL SANDERS PEPER MARTIN, LLP		
Signature			
Printed Name	MARK F. WACHTER		
Date	March 24, 2006	Reg. No.	27,243

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. <b>EV528424207US</b>			
Signature			
Typed or printed name	Jennifer J. Wheatley	Date	3/24/2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 4

**Complete if Known**

Application Number	10/709,870
Filing Date	June 2, 2004
First Named Inventor	Mitchell I. Kirschner
Art Unit	1616
Examiner Name	Frank I. Choi
Attorney Docket Number	718689.78

**U.S. PATENT DOCUMENTS**

Examiner Initials'	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)				
	A1	US- 2,491,452		12-13-1949	Kern et al.	
	A2	US- 4,656,028		04-07-1987	Cuca, Robert C.	
	A3	US- 4,690,816		09-01-1997	Paradissis et al.	
	A4	US- 4,772,472		09-20-1988	Schönmann et al.	
	A5	US- 4,874,629		10-17-1989	Chang et al.	
	A6	US- 4,891,172		01-2-1990	Matsushita et al.	
	A7	US- 4,935,243		06-19-1990	Borkan et al.	
	A8	US- 5,071,643		12-10-1991	Yu et al.	
	A9	US- 5,141,961		08-25-1992	Coapman, Scott D.	
	A10	US- 5,200,191		04-06-1993	Steele et al.	
	A11	US- 5,246,635		09-21-1993	Ratko et al.	
	A12	US- 5,360,615		11-01-1994	Yu et al.	
	A13	US- 5,422,160		06-06-1995	Ratko et al.	
	A14	US- 5,565,214		10-15-1996	Zambo et al.	
	A15	US- 5,641,512		06-24-1997	Cimiluca, Paul A.	
	A16	US- 5,827,535		10-27-1998	Stone, Dan D.	
	A17	US- 5,869,084		02-09-1999	Paradissis et al.	
	A18	US- 6,077,828		06-20-2000	Abbruzzese et al.	
	A19	US- 6,258,846		07-10-2001	Hermelin et al.	
	A20	US- 6,346,231		02-12-2002	Opheim, Joar	
	A21	US- 6,471,969		10-29-2002	Schlachter et al.	
	A22	US- 2005/0037065 A1		02-17-2005	Kirschner et al.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/709,870	
			Filing Date	June 2, 2004	
			First Named Inventor	Mitchell I. Kirschner	
			Art Unit	1616	
			Examiner Name	Frank I. Choi	
Sheet	2	of	4	Attorney Docket Number	718689.78

FOREIGN PATENT DOCUMENTS						
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	B1	JP 54-35210	03-15-1979	Seo et al.		
	B2	GB 2,223,943	04-25-1990	Tillotts Pharmaceutical AG		
	B3	GB 2,254,556	10-14-1992	Fisons plc		
	B4	JP 5-139959	06-08-1993	EISAI Co. LTD.		
	B5	WO 9704668 A2	02-13-1997	Schlachter et al.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	STN/CAS Online, file CAPLUS, Acc. No. 1989:462736, Doc. No. 91:62736; Seo et al.; "Soft capsules of unsaponifiable substances of vegetable oils"; JP 54035210 A2; Abstract.	
	C2	Database CAPLUS on STN, No. 1993:525229; KATO et al.; "Soft Capsules containing water-soluble pharmaceuticals;" JP 05139959 A (Kato et al.) June 8, 1993, Abstract.	
	C3	STN/CAS online, file PROMT, Acc. No. 97:437691; Mont, "Brittle and Twisted;" Chemist & Druggist (Text); July 5, 1997; page 1.	
	C4	STN/CAS online, file PROMT, Acc. No. 83:40219; "Manufacturing Chemist & Aerosol News"; Abstract; March 1983; pages 56-591; Abstract.	
	C5	VITAMIN RESEARCH DEPT.; "Can adults adequately convert alpha-linolenic acid (18:3n-3) to eicosapentaenoic acid (20:5n-3) and docosahexaenoic acid (22:6n-3)?" Int J. Vitam Nutr Res (Text); 1998; 68(3): 159-73; F. Hoffman-Roche Ltd; Basel, Switzerland; Text.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/709,870		
		Filing Date	June 2, 2004		
		First Named Inventor	Mitchell I. Kirschner		
		Art Unit	1616		
		Examiner Name	Frank I. Choi		
Sheet	3	of	4	Attorney Docket Number	718689.78

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C6	FAN, YY & CHAPKIN, RS; "Importance of dietary gamma-linolenic acid in human health and nutrition"; Int. J. Vitam Nutr Res. (Text); Sept. 1998; 128(9): 1411-4; Faculty of Nutrition, Molecular & Cell Biology Group, Texas A&M University; Texas.	
	C7	MEYDANI ET AL.; "Food use and health effects of soybean and sunflower oils"; J Am Coll Nutr (Text); October 1991; 10(5): 406-28; USDA Human Nutrition Research Center on Aging, Boston, Massachusetts.	
	C8	Remington's Pharmaceutical Sciences; 1985; page 328; 17th Edition.	
	C9	FOOD AND DRUG ADMINISTRATION; "Amino Acid Supplements: What you need to know"; <a href="http://vanderbiltowc.wellsources.com">http://vanderbiltowc.wellsources.com</a> ; August 2004; 3 pages; Food and Drug Administration.	
	C10	Physicians' Desk Reference; 1999; Page 3128 53d Ed.	
	C11	Physicians' Desk Reference; 1999; Page 3163; 53d Ed.	
	C12	Physicians' Desk Reference; 1999; Page 3212; 53d Ed.	
	C13	Physicians' Desk Reference; 1999; Pgs. 2811-2812; 53d Ed.	
	C14	Physicians' Desk Reference; 1999; Page 1011; 53d Ed.	
	C15	Physicians' Desk Reference; 1999; Pages 1522-3; 53d Ed.	
	C16	Physicians' Desk Reference; 1999; Page 1692; 53d Ed.	
	C17	Physicians' Desk Reference; 1999; Page 2802; 53d Ed.	
	C18	Physicians' Desk Reference; 1999; Pages 2916-7; 53d Ed.	
	C19	Physicians' Desk Reference; 1999; Pages 2917-8; 53d Ed.	
	C20	The Merck Manual; 1992; Page 749; 16 <sup>th</sup> Ed.	
	C21	The Merck Manual; 1992; Pages 1850-1866; 16 <sup>th</sup> Ed.	
	C22	OLANS, et al.; "Gastroesophageal Reflux. In Pregnancy"; Gastrointest Endosc. Clin. N. Am. 4(4); 1994; 4 Pages 699-712.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/709,870		
		Filing Date	June 2, 2004		
		First Named Inventor	Mitchell I. Kirschner		
		Art Unit	1616		
		Examiner Name	Frank I. Choi		
Sheet	4	of	4	Attorney Docket Number	718689.78

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C23	BROUSSARD, ET AL.; "Treating Gastroesophageal Reflux Disease during Pregnancy and Lactation: What are the safest therapy options"; Drug Safe 19(4); 1998; Pages 325-337.	
	C24	Physicians' Desk Reference; 1999; Pages 2526-2527; 53d Ed.	
	C25	KATZ, ET AL.; "Gastroesophageal Reflux Disease during Pregnancy"; Gastroenterol. Clin. North Am. 27(1); 1998; Pages 153-167.	
	C26	NEBEL, ET AL.; "Symptomatic Gastroesophageal Reflux; Incidence and Precipitating Factors"; Am. J. Dig. Dis. 21(11); 1976; Pages 953-956.	
	C27	MORTON, KOUSEN, M.D.; "Treating Nausea and Vomiting in Pregnancy"; Am. Family Physician 48(7); 1993; Pages 1279-1284.	
	C28	"Understanding Nutrition"; Whitney and Rolfes Eds.; 1993; Pages 479-480; 6 <sup>th</sup> Ed.	
	C29	SCHORAH, ET AL.; "Importance of Adequate Folate Nutrition in Embryonic and Early Fetal Development Vitamins and Minerals in Pregnancy and Lactation"; Berger Ed.; 1988; Pages 167-176.; Vol. 16.	
	C30	SMITHELLS, ET AL.; "Vitamin Deficiencies and Neural Tube Defects"; Arch. Dis. Child; 1976 Pages 51:944-950.	
	C31	"Van Nostrand's Scientific Encyclopedia"; 1983; Page 2891; 6 <sup>th</sup> Ed.	
	C32	OTTO, S. J., ET AL.; "Maternal and Neonatal Essential Fatty Acid Status in Phospholipids: An International Comparative Study, European Journal of Clinical Nutrition"; April 1997; Pages 232-242; Vol. 51 #4.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450: DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.